AF/3732

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(to be used for all correspondence after initial filing)

Application Number	09/815,567
Filing Date	March 23, 2001
First Named Inventor	Fred T. Parker
Art Unit	3732
Examiner Name	Anuradha Ramana
Total Number of Pages in This Submission: 38	Attorney Docket Number: 8627/096

ENCLOSURES (*Check all that apply*)

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
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Remarks

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Lawrence A. Steward, Reg. No. 32,309 BRINKS HOFER GILSON & LIONE
Signature	Lawrence A. Steward
Date	July 18, 2003

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FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 320.00

Complete if Known	
Application Number	09/815,567
Filing Date	March 23, 2001
First Named Inventor	Fred T. Parker
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Art Unit	3732
Attorney Docket No.	8627/096

METHOD OF PAYMENT *(check all that apply)*

☑ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

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Deposit Account Number: 23-1925

Deposit Account Name: Brinks Hofer Gilson Lione

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims		-20** =		x =
Independent Claims		- 3** =		x =
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	320
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 320.00

SUBMITTED BY				(Complete *if applicable*)	
Name (Print/Type)	Lawrence A. Steward	*Registration No. (Attorney/Agent)*	32,309	*Telephone* 317-636-0886	
Signature				*Date*	July 18, 2003

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on July 18, 2003

Carolyn Beason-Wright

Carolyn Beason-Wright

T-H. 7-29-03 # 15/Brief

PATENT

Case No. 8627/096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	)	
	)	Art Unit: 3732
Fred T. Parker	)	
	)	Examiner: Anuradha Ramana
Serial No.: 09/815,567	)	
	)	
Filed: March 23, 2001	)	
	)	
For: INTRODUCER SHEATH	)	

BRIEF OF APPELLANT

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal is taken from the decision of the Examiner dated February 20, 2003, finally rejecting claims 1-21 of the present application. Appellant timely filed his Notice of Appeal to the final rejection on May 19, 2003.

I. REAL PARTY IN INTEREST

The real party in interest in this matter is the Assignee of the application, Cook Incorporated.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to Appellant or Appellant's legal representatives which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant matter.

III. STATUS OF CLAIMS

Claims 1-21 were presented for examination.

Claims 1-21 stand finally rejected and are appealed herein.

No claims have been canceled.

IV. STATUS OF AMENDMENTS

A Response After Final Action was mailed by Appellant on April 18, 2003. The Response included arguments in support of the patentability of the claims, however no claims were amended. The rejections were maintained by the Examiner.

V. SUMMARY OF INVENTION

The present invention describes a flexible, kink-resistant, introducer sheath having a flexible distal tip portion.

Introducer sheaths are well known for percutaneous vascular access. Such sheaths can be of thin-walled construction, and are prone to kinking as they pass through the body vessel. When a sheath kinks in a body vessel, the sheath is unusable and must be removed from the patient. Increasing the thickness of the sheath only minimally improves the level of kink resistance, while at the same time undesirably enlarging the entry hole.

The present inventor disclosed an introducer sheath with improved kink resistance in U.S. Patent No. 5,380,304. This sheath comprises respective inner and outer tubes, and includes a coil that is compression-fitted around an inner tube. In this design, the distal ends of the inner and outer tubes extend beyond the distal end of the coil, and the distal end of the outer tube is tapered and extends beyond the distal end of the inner tube to prevent the inner tube from presenting a rough edge or surface to the vessel wall. The outer tube comprises a heat-formable polyamide

material such as nylon for connecting with the rough outer surface of the inner tube, between the coil turns. In order to facilitate entry into the percutaneous access site, a distal tip member that is of the same durometer, or harder, than the outer tube is bonded onto the distal end of the outer tube. (P. 2, lines 1-18, and Figs. 1 and 2.) Although a sheath having a high durometer tip is effective for facilitating entry into many percutaneous access sites, such tips are not desirable in all instances. For example, when a tortuous path through the body must be traversed, or when highly sensitive treatment sites must be accessed, a softer, more flexible distal tip portion is desired.

The introducer sheath of the present invention includes an inner tube made from a polymer such as polytetrafluoroethylene, and a wire coil wound around the inner coil. A first, proximal length of outer tubing of a relatively hard material such as nylon extends along most of the length of the coil-wound inner tube. A second, distal length of outer tubing having a *softer* durometer than the first length of outer tubing is placed over the remainder of the exposed coil-wound length of the inner tube, and abuts the end of the first length of outer tubing. Both the first and second lengths of outer tubing can be melted to flow between the spacings of the coil wire to bond to the outer surface of the inner tube, and to thermally bond to each other at the abutment location. The distal end of the second outer tubing length is tapered, and the sheath is fabricated having a flexible distal tip portion. The inventive introducer sheath is capable of use in applications involving tortuous vascular paths, such as renal and other arterial applications, and in uses where an atraumatic flexible kink-resistant distal tip portion is desired. (P. 2, line 23- P.3, line 12.)

VI. ISSUES

1. Are claims 1-2, 4-5, 10-13 and 15-20 unpatentable under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187)?

2. Is claim 3 unpatentable under 35 U.S.C. 103(a) over Horrigan et al. in view of Park et al. as applied to claim 1, and further in view of Parker (US 5,380,304)?

3. Are claims 6-9 and 21 unpatentable under 35 U.S.C. 103(a) over Horrigan et al. in view of Park et al., further in view of JU (US 5,599,325)?

4. Is claim 14 unpatentable under 35 U.S.C. 103(a) over Horrigan et al. in view of Park et al as applied to claim 1 above, further in view of MacDonald et al. (US 6,210,396)?

VII. GROUPING OF CLAIMS

All of the claims in this application stand or fall together.

VIII. ARGUMENT

Issue 1.

Claims 1-2, 4-5, 10-13 and 15-20 are not unpatentable under 35 U.S.C. 103(a) over Horrigan et al. in view of Park et al.

According to the Examiner in the final Office Action mailed February 20, 2003, the patent to Horrigan discloses a catheter or sheath having features in common with the claimed invention, but does not disclose a device having a flat wire coil as a reinforcement means. The patent to Park was cited as a secondary reference for its teaching of a catheter section having a "braided wire coil."

The present invention is directed to an introducer sheath. Two desirable features of an introducer sheath are that the sheath have a thin-walled construction so that the opening in the body for percutaneous entry can be as small as possible, and that the sheath be resistant to kinking so that it can be advanced through tortuous body passageways and/or directed to more sensitive treatment sites.

Notwithstanding these desirable features, Horrigan chose to utilize a wire braid as a reinforcement means in his reinforced catheter, rather than a wire coil as used in the present invention. Although wire braids and wire coils may be

considered relatively interchangeable in some instances, there are certain instances when the differences between them can be very significant. For example, a braided reinforcement has an enlarged diameter when compared to a wire coil. This enlarged diameter results from the crossing of the wire strands that make up the braided pattern. Thus, when reinforcing wire having a 0.002 inch diameter is used, the effective diameter of the windings of a coil made of such wire is 0.002 inch. Since a braid includes crossings of this wire, the effective diameter at the crossings of a braid made of such wire is 0.004 inch, or twice that of the wire coil. When a key objective of such introducer sheaths is to achieve smaller and smaller diameters, the use of a wire coil is advantageous when compared to the use of a braid.

In addition to the foregoing, a wire coil has greater kink resistance than a wire braid. Flexibility at the distal end is often an important feature of an introducer sheath, particularly when the sheath is used to access tortuous passageways. For a sheath to be able to bend in those passageways without kinking, the sheath material on the outer part of the bend must stretch, and the corresponding sheath material on the inner part of the bend must compress. The very nature of a braid (overlapping woven fibers or filaments) is such that it resists substantial expansion and compression. The mere combination of lower durometer materials with a braid reinforcement does not overcome this deficiency. In fact, this combination largely defeats the purpose of using lower durometer materials in the first place since it results in a tube that is only marginally more flexible. The use of a coil reinforcement, on the other hand, can elongate or increase the distance between the turns on the outside of the bend very easily with minimum force. Combining the coil reinforcement with the lower durometer distal sheath material results in a tube structure that is much more flexible and kink resistant than when a braided reinforcement is used.

In contrast, the use of a wire braid reinforcement is known to provide favorable torsional control when compared to a wire coil (torsional control being a stated objective of Horrigan). Thus, it is clear that Horrigan was addressing problems relating to the introduction of medical devices into the body from an

entirely different perspective than was the applicant herein, and his disparate solutions to those problems reflect that different direction.

In addition to the foregoing advantages, a further advantage of the use of a wire coil reinforcement in an introducer sheath when compared to a braided reinforcement is the ease of manufacture of the sheath. When a braid is utilized, it is generally necessary to fuse or otherwise bond (at least) the ends of the braid to the inner liner. Otherwise, the high tensile strength of the braid tends to cause the braid to spring outwardly and not wrap around the liner. In addition, the terminal ends of a braid are prone to fraying. This requires the ends of the braid to be well-bonded or fused to the outer wall of the inner liner to avoid such frayed ends. A wire coil, on the other hand, may simply be compression fitted around the inner liner within the outer tube. Normally, no fusing or bonding of the coil (as in Horrigan), or its ends, is required. As a result, the use of a wire coil reinforcement rather than a wire braid in an introducer sheath reduces the cost of manufacture of the sheath.

The patent to Park teaches a catheter section that is capable of self-forming a selected shape upon application of heat and retaining that shape upon cooling. Specifically, the catheter section includes in its wall a forming member which comprises a super-elastic nickel-titanium (nitinol) alloy. The catheter section is formed in a first shape, and is then restrained in a polymeric outer sheath in a second shape under non-equilibrium conditions. When the polymeric outer layer is heated (and thereby softened), the catheter section re-assumes the shape given to it during the heat treatment step.

Park prefers to use super-elastic nitinol ribbon braids for reinforcement because of their ability to retain non-elastic strain and return to a prior form upon release of the polymeric restraint. Col. 7, lies 55-58. Although sheaths using super-elastic braids can be beneficial in certain defined instances, they can be complicated to use. Such sheaths require that certain known and pre-configured shapes be formed, and that certain working temperatures be used. This reference deals with the problem of accessing remote anatomical areas in a completely different, and much more complex, manner than the present invention. Although Park mentions that kink-resistance is a desirable feature of his catheters, he does not teach or

suggest the straightforward manner in which the problem is addressed in the present invention.

As stated, the present invention utilizes a wire coil (rather than a wire braid), to obtain the advantages of, among others, kink resistance, small wall diameter and low manufacturing cost. The Horrigan reference neither teaches nor suggests an optimal manner of achieving such advantages, and in fact, by its use of a reinforcement braid, teaches away from such advantages. Park teaches a complex solution to the problem of access through increasingly small vessels that is very different than the present invention. Neither of these references, either individually or in combination, achieves the simple solution that is provided when a coil is used, as in the present invention.

Appellant respectfully submits that absent the use of hindsight gleaned from the teachings of the present invention, one skilled in the art would not combine such disparate teachings. Neither reference provides any motivation to solve the problems of accessing tortuous passageways and/or sensitive treatment sites in the simple, straightforward and cost-effective manner of the claimed invention. Since they are either directed to other problems (Horrigan), or to other, complex solutions to vascular access problems (Park), the cited references also do not provide any motivation for making the combination cited by the Examiner.

Therefore, for all of the foregoing reasons, Appellant respectfully submits that claims 1-2, 4-5, 10-13 and 15-20 are not obvious in view of the cited combination.

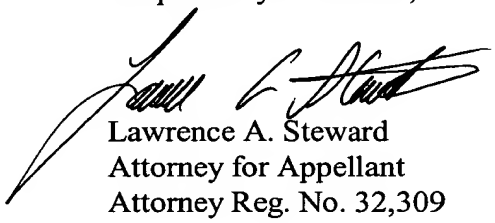
Issues 2, 3 and 4.

Dependent claims 3, 6-9, 14 and 21 include all of the limitations of claim 1, and are allowable for at least the same reasons that claim 1 is allowable. Claim 21 is an independent claim. This claim includes the relevant limitations of claim 1, and is also allowable for at least the same reasons that claim 1 is allowable.

IX. CONCLUSION

For the foregoing reasons, Appellant respectfully submits that the grounds for the Examiner's rejections of claims 1-21 are not well taken, and should be reversed by this Board.

Respectfully submitted,



Lawrence A. Steward
Attorney for Appellant
Attorney Reg. No. 32,309

LAS/cbw

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APPENDIX OF CLAIMS

1. An introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end;

a first outer tube disposed around said wire coil and said inner tube therewithin to a first outer tube distal end spaced proximally from said wire coil distal end such that a distal end portion of said wire coil extends distally therebeyond; and

at least a second outer tube disposed around said wire coil and said inner tube therewithin extending distally from said first outer tube distal end and covering said distal end portion of said wire coil and extending slightly beyond said distal end of said inner tube,

said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material of a substantially softer durometer than said material of said first outer tube.

2. The introducer sheath according to claim 1, wherein said outer tube and said inner tube are bonded to each other and to said wire coil and to said inner tube between windings of said wire coil.

3. The introducer sheath according to claim 2, wherein an outwardly facing surface of said inner tube has been roughened to enhance bonding thereto of said first and second outer tubes.

4. The introducer sheath according to claim 2, wherein said bonding is heat bonding.

5. The introducer sheath according to claim 1, wherein a radiopaque marker band is affixed to said wire coil distal end within said second outer tube.

6. The introducer sheath according to claim1, wherein said second outer tube is polymeric and contains radiopaque filler.

7 The intravascular sheath according to claim 6, wherein said second outer tube contains between about 20% and 85% by weight of radiopaque filler particles.

8. The introducer sheath according to claim 6, wherein said second outer tube contains about 80% by weight of radiopaque filler particles.

9. The introducer sheath according to claim 1, wherein said first outer tube is substantially free of radiopaque filler.

10. The introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of at least 5 D lower than that of the material of the first outer tube.

11. The introducer sheath according to claim 10, wherein said first outer tube comprises a material having a durometer of about 56D to 58D.

12. The introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of between about 10 D and 75 D.

13. The introducer sheath according to claim 12, wherein said second outer tube comprises a material having a durometer of about 39D.

14. The introducer sheath according to claim 1, wherein said first and second outer tubes are distinctly different in color or shade.

15. The introducer sheath according to claim 1, wherein said wire coil comprises flat wire.

16. The introducer sheath according to claim 1, wherein a distal tip region of the sheath is arcuate.

17. The introducer sheath according to claim 16, wherein said arcuate distal tip region has a length of about 1 cm or more.

18. The introducer sheath according to claim 16, wherein said arcuate distal tip region extends about an angle of about 90°.

19. The introducer sheath according to claim 1, wherein said wire coil extends for a length of about five millimeters beyond said distal end of said first outer tube.

20. The introducer sheath according to claim 1, wherein said inner tube is unitarily formed.

21. An introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end;

a first outer tube disposed around said wire coil and said inner tube therewithin to a first outer tube distal end spaced proximally from said wire coil distal end such that a distal end portion of said wire coil extends for a length of about 1 cm distally therebeyond; and

a second outer tube distally from said first outer tube distal end and disposed around and covering said distal end portions of said wire coil and said inner tube therewithin and extending slightly therebeyond;

said first outer tube being of a material having a durometer of between about 50 D and 60 D, and said second outer tube being of a material of a durometer of between about 35 D and 45 D;

said second outer tube comprises a radiopaque material;

said wire coil is of flat wire;

said first and second outer tubes are bonded to said inner tube and to said wire coil.